August 25, 2020

Tiffany Swygert, Director,
Division of Outpatient Care
Centers for Medicare and Medicaid Services
7500 Security Blvd,
Baltimore, MD 21244-1850

Re: New Technology Ambulatory Payment Classification (APC) for the Surfacer Device

Dear Ms. Swygert,

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease. We are writing with regard to CMS coverage of new technology in the area of hemodialysis access.

RPA is writing to support the application for New Technology Ambulatory Payment Classification (APC) for the Surfacer Device. The procedure described in the application is termed: Insertion of Central Venous Access Catheter using a reverse central venous recanalization device, with fluoroscopic image guidance.

This new technology developed by Bluegrass Vascular addresses a very important problem for patients, who need central venous access, and especially our Chronic Kidney Disease patients who require hemodialysis access. Nephrologists, vascular surgeons, and interventional radiologists who place Central Venous dialysis catheters (CVC) typically utilize the internal jugular veins for entry to the thoracic central veins (jugular, brachiocephalic and superior vena cava). These catheters have a limited useful functionality and should be removed as soon as a better permanent access can be achieved. Often, however, over time multiple catheters are required to maintain access in a complicated patient. These catheters damage the veins and cause scarring which leads to stenosis or complete obstruction. These obstructions may even completely occlude the central veins preventing the typical placement of a new dialysis catheter and instead require new suboptimal translumbar, transhepatic or femoral vein locations. The inability to successfully place a CVC can even result in death particularly in hemodialysis patients.
The Surfacer device helps to solve the problem of complete obstruction of the right internal jugular vein, brachiocephalic vein and/or superior vena cava by using an entirely different approach and new technique which ultimately results in a functioning CVC which emerges from the base of the right neck, but originates from inside the central veins. This technology is a major advancement to patient care.

RPA believes that there is no existing CPT code that correctly describes the Surfacer Procedure and its attendant work and risks. Indeed, it is inappropriate to report this procedure with existing catheter placement codes. Our subsequent comments will expand on this position and make recommendations regarding coding options.

The catheter codes (36556 and others in the code family) describe the direct external puncture of a native vein (typically the internal jugular for dialysis access) through the skin and using the Seldinger Technique advancing a catheter antegrade over a guidewire or through a sheath into the central veins or right atrium. Ultrasound guidance is typically used for needle puncture and placement into the vein. Fluoroscopy may additionally be used to guide wire and catheter placement.

In contrast, the Surfacer procedure is performed only when there is complete obstruction of the targeted central veins. It requires cannulation of the femoral vein in the right groin and then passage of a wire and catheter through the iliac vein, inferior vena cava, right atrium, and superior vena cava to reach the proximal obstruction in the thoracic central vein(s). Angiography (and at times more advanced imaging such as CT angiography) is required to place the wire, to define the level of obstruction and to safely recanalize the vessel. Once the obstruction is identified, the catheter is exchanged for a more rigid, reinforced guiding sheath and its tip is located just proximal to the obstruction. The operator advances the Surfacer device from the leg through the sheath to the obstructed central vein and then punctures through the intrathoracic obstruction in a retrograde direction and until the device exits the supraclavicular skin; thus, the inside-out description. A sheath is then drawn from the exterior, through the skin into the central veins so that a catheter (or other device) can be introduced from the outside. While this is ultimately an internal Jugular vein CVC, it has been positioned by a vastly different procedure. The time and risks involved in recanalizing an occluded central vein to create catheter access in this inside-out manner are far greater than standard catheter placement technique.

The Surfacer procedure uses unique technology to recanalize an occluded central vein, and to accomplish placement of a CVC from an inside out approach. Indeed, the Surfacer procedure is likely to be used to recanalize occluded central veins for placement of many other devices including non-tunneled central venous catheter (36556), tunneled central venous catheter (36558), and tunneled central venous catheter with subcutaneous port (36561), as well as pacemakers, defibrillators and the like.

RPA believes that CPT will develop a code descriptor that is more specific to the Surfacer procedure (e.g. “Recanalization of obstructed central vein to obtain central venous access,
from retrograde inside-out approach” and that the procedure would be coded separately from the catheter placement. In the interim, the Surfacer procedure should be given a unique HCPCS C-code and assigned to a New Technology APC. This will allow it to be appropriately reported, and more importantly, to be used to achieve central venous access in severely compromised people.

In summary, we strongly support the Surfacer device as a new technology procedure extremely important to a broad spectrum of patients, and especially those requiring hemodialysis through a catheter. We believe that assignment to a New Technology APC would be appropriate for this very complex procedure.

As always, RPA welcomes the opportunity to work collaboratively with CMS in its efforts to improve the quality of care provided to the nation’s kidney patients, and we stand ready as a resource to CMS in its future work on hemodialysis access. Any questions or comments regarding this correspondence should be directed to RPA’s Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at rblaser@renalmd.org.

Sincerely,

Jeffrey A. Perlmutter, MD
President